

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MAUREEN TOOMEY,

Plaintiff,

VS.

No. 07 CV 7173

SANOFI-AVENTIS U.S. INC. f/k/a AVENTIS
PHARMACEUTICALS, INC., f/k/a HOECHST
MARION ROUSSEL, INC.;
WALGREEN CO.;
BOND DRUG COMPANY OF ILLINOIS d/b/a
WALGREEN CO., a Corporation

Judge Blanche M. Manning
Magistrate Judge Martin C. Ashman

Defendants.

**ANSWER, JURY DEMAND AND AFFIRMATIVE DEFENSES OF BOND DRUG
COMPANY OF ILLINOIS, LLC d/b/a WALGREENS (INCORRECTLY SUED AS
WALGREEN CO. and BOND DRUG COMPANY OF ILLINOIS d/b/a
WALGREEN CO.)**

Now Comes BOND DRUG COMPANY OF ILLINOIS, L.L.C. d/b/a WALGREENS, incorrectly sued as WALGREEN CO. and BOND DRUG COMPANY OF ILLINOIS d/b/a WALGREEN CO., by and through its attorneys, John A. Childers and Michael C. Holy, for its Answer, Jury Demand and Affirmative Defenses (“Answer”) to Plaintiff’s Complaint as follows:

1. That prior to August 24, 2005, SANOFI-AVENTIS was a manufacturer of many prescription drugs, including, but not limited to, the drug commonly referred to as Ketek.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 1 of Plaintiff's Complaint.



2. That prior to August 24, 2005, WALGREENS was a distributor of many prescription drugs, including, but not limited to, the drug commonly referred to as Ketek.

ANSWER: This Defendant admits that it sold the prescription drug Ketek® as well as other prescription drugs to some of its retail pharmacy customers on and prior to August 24, 2005. This Defendant denies all remaining allegations contained on Paragraph 2 of Plaintiff's Complaint.

3. That on or about August 24, 2005, KIMBERLY RICUARTE was a licensed physician in the State of Illinois and all of its branches.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 3 of Plaintiff's Complaint.

4. That on or about August 24, 2005, KIMBERLY RICUARTE prescribed a drug for MAUREEN TOOMEY commonly referred to as Ketek, 400 mg. for sinusitis.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 4 of Plaintiff's Complaint.

5. That on or about August 24, 2005, MAUREEN TOOMEY filled a prescription for Ketek, 400 mgs. at WALGREENS, 2100 Green Bay Road, Evanston, Illinois, 60201.

ANSWER: This Defendant admits that its records indicate a prescription for 400 mg Ketek® was purchased at a "Walgreens" store at or about 2100 Green Bay Road in Evanston, Illinois for a Maureen C. Toomey on or about August 24, 2005. In further

answer, this Defendant denies all remaining allegations contained in Paragraph 5 of Plaintiff's Complaint.

6. That on or about August 24, 2005, MAUREEN TOOMEY consumed the prescription drug commonly referred to as Ketek, 400 mg. until about mid-September, 2005.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 6 of Plaintiff's Complaint.

7. That on or about September 11, 2005, MAUREEN TOOMEY's urine became dark, and she began to have other symptoms including nausea.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 7 of Plaintiff's Complaint.

8. That on or about September 11, 2005, MAUREEN TOOMEY, was treated by Emily Gottlieb, M.D., who performed a urinalysis.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 8 of Plaintiff's Complaint.

9. That on or after September 11, 2005, results from the urinalysis of MAUREEN TOOMEY found bile in her urine and stones in her gallbladder.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 9 of Plaintiff's Complaint.

10. That on or about September 16, 2005, MAUREEN TOOMEY was admitted to Evanston Hospital.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 10 of Plaintiff's Complaint.

11. That on or about September 16, 2005, Evanston Hospital, through an agent or employee, performed an ERCP which revealed MAUREEN TOOMEY had pancreatitis and an unknown caused hepatitis.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 11 of Plaintiff's Complaint.

12. That on or about October 21, 2005, MAUREEN TOOMEY was re-admitted to Evanston Hospital.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 12 of Plaintiff's Complaint.

13. That on or about October 21, 2005, a CT scan of MAUREEN TOOMEY determined she had an extremely enlarged gallbladder from the hepatitis.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 13 of Plaintiff's Complaint.

14. That on or about October 21, 2005 continuing through December 12, 2005, MAUREEN TOOMEY was treated with Augmentin.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 14 of Plaintiff's Complaint.

15. That on or about December 12, 2005, MAUREEN TOOMEY was admitted to Evanston Hospital for laparoscopic surgery.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 15 of Plaintiff's Complaint.

16. That in late February, 2006, MAUREEN TOOMEY started to experience arthralgia, and consulted with Emil Gottlieb, MD., and a neurologist at Evanston Hospital, and it was determined she had carpal tunnel syndrome.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 16 of Plaintiff's Complaint.

17. That on or about May 9, 2006, MAUREEN TOOMEY was treated by Richard M. Green, M.D., of Northwestern Memorial Hospital, and he diagnosed MAUREEN TOOMEY with autoimmune Hepatitis.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 17 of Plaintiff's Complaint.

18. That on or about May 12, 2006, MAUREEN TOOMEY checked into the Mayo Clinic of Rochester, Minnesota, where they prescribed her with 40 mg. of Prednisone.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 18 of Plaintiff's Complaint.

19. That in August, 2006, MAUREEN TOOMEY was treated by Cheryl Wilkes, M.D., who told her she could not return to work due to the stress.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 19 of Plaintiff's Complaint.

20. That in November 2006, MAUREEN TOOMEY was treated by Mark Moltch, M.D., and he told her all of her medical problems had returned.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 20 of Plaintiff's Complaint.

21. That on or about January 12, 2007, MAUREEN TOOMEY was treated by Christy Park, M.D., who diagnosed her with inflammatory poly arthritis, which was a complication of her autoimmune hepatitis.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 21 of Plaintiff's Complaint.

22. That on and prior to August 24, 2005, the drug manufacturer, SANOFI-AVENTIS, knew the drug Ketek caused adverse reactions including hepatitis, jaundice, chronic pain, as well as carpal tunnel syndrome, and is only to be used in mild to moderate cases of community-acquired pneumonia.

ANSWER: Paragraph 22 is not directed against this Defendant, and as such, no answer is required. If an answer is deemed necessary, this Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 22 of Plaintiff's Complaint.

23. That on and prior to August 24, 2005, the drug manufacturer, SANOFI-AVENTIS, was aware patients were prescribed and took Ketek were experiencing adverse reactions including hepatitis, jaundice, chronic pain, as well as carpal tunnel syndrome, and should not be used for sinusitis.

ANSWER: Paragraph 23 is not directed against this Defendant, and as such, no answer is required. If an answer is deemed necessary, this Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 23 of Plaintiff's Complaint.

24. There prior to August 24, 2005, there was no warning in the Physician's Desk Reference on the package insert for a drug commonly referred to as Ketek

regarding adverse reactions including hepatitis, jaundice, chronic pain, as well as carpal tunnel syndrome, and should not be used for sinusitis.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 24 of Plaintiff's Complaint.

25. That prior to August 24, 2005, there were no warnings to physicians, and consumers including the plaintiff from SANOFI-AVENTIS about Ketek causing adverse reactions including hepatitis, jaundice, chronic pain, as well as carpal tunnel syndrome, and should not be used for sinusitis.

ANSWER: Paragraph 25 is not directed against this Defendant, and as such, no answer is required. If an answer is deemed necessary, this Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 25 of Plaintiff's Complaint.

26. That on or about August 24, 2005, the package insert regarding the drug Ketek received by the pharmacist at WALGREENS and the Plaintiff, was in the same condition as when it left the manufacturer's, WALGREENS, control.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 26 of Plaintiff's Complaint. In further answer, this Defendant specifically denies, however, that it was the manufacturer of Ketek®.

27. That on or about August 24, 2005, the package insert regarding the drug Ketek and the drug Ketek given to MAUREEN TOOMEY by the pharmacist at

WALGREENS did not include any warnings about Ketek causing adverse reactions including hepatitis, jaundice, chronic pain, as well as carpal tunnel syndrome, and should not be used for sinusitis.

ANSWER: This Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 27 of Plaintiff's Complaint.

28. That on and prior to August 24, 2005, the manufacturer and distributor of prescription drugs had a duty to warn consumers such as MAUREEN TOOMEY of the dangers and adverse reactions of those drugs as well as indications for use.

ANSWER: Paragraph 28 of Plaintiff's Complaint alleges legal conclusions. To the extent an answer is required, it denies that paragraph 28 of Plaintiff's Complaint accurately alleges the duty of one who distributes prescription drugs to consumers. Except as stated herein, Paragraph 28 of Plaintiff's Complaint is denied.

29. That the drug Ketek was unreasonably dangerous in one or more of the following respects:

- a) Did not warn about the side effects of Ketek including jaundice and chronic pain, or
- b) Did not warn against the adverse reaction of hepatitis and carpal tunnel syndrome; or
- c) Did not include that Ketek is only to be used in mild to moderately severe cases of community-acquired pneumonia; or
- d) Was otherwise unreasonably dangerous.

ANSWER: Paragraph 29 of Plaintiff's Complaint alleges legal conclusions. To the extent an answer is required, it denies the allegations contained in Paragraph 29 of Plaintiff's Complaint.

30. That as a proximate result of one or more of the foregoing unreasonably dangerous conditions, MAUREEN TOOMEY was injured, has experienced pain and suffering; has been disabled and disfigured; has incurred expenses for medical, prescription, therapy, and other similar expenses; and has lost wages.

ANSWER: This Defendant denies any wrongful conduct pertaining to Plaintiff, and further denies that it caused or contributed to Plaintiff's alleged injuries or damages, if any, and therefore, denies all allegations contained in Paragraph 30 of Plaintiff's Complaint.

WHEREFORE, Defendant denies that it caused or contributed to Plaintiff's alleged injuries, if any, denies that Plaintiff is entitled to any damages from this Defendant and, therefore, denies all allegations contained in such Paragraphs of Plaintiff's Complaint.

AFFIRMATIVE DEFENSES

FIRST DEFENSE

The injuries and damages allegedly suffered by Plaintiff in this action, if any, were or may have been due to the contributory and/or comparative negligence of Plaintiff, and/or those acting at her direction or control, in failing to exercise due and proper care under the existing circumstances and conditions, thereby barring recovery or reducing her damages by the doctrines of contributory or comparative negligence.

SECOND DEFENSE

The injuries and damages allegedly suffered by Plaintiff in this action, if any, to the extent not caused by the negligence or fault of Plaintiff, may have been proximately caused by the negligence, fault, action or inactions of persons or entities other than this Defendant, over whom this Defendant had no control, and for such negligence, faults, actions or inactions, this Defendant is not responsible.

THIRD DEFENSE

The injuries and damages allegedly suffered by Plaintiff in this action, if any, were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug of pharmaceutical preparation sold by this Defendant or other sellers, thereby barring Plaintiff from recovery.

FOURTH DEFENSE

The injuries and damages allegedly suffered by Plaintiff in this action, if any, were not proximately caused by the use of Ketek® or by any acts or omissions on the part of this Defendant.

FIFTH DEFENSE

The injuries and damages allegedly suffered by Plaintiff in this action, if any, were caused directly, solely and proximately by sensitivities, medical conditions and idiosyncrasies peculiar to Plaintiff not found in the general public, and were unknown, unknowable or not reasonably foreseeable to this Defendant.

SIXTH DEFENSE

The injuries and damages allegedly suffered by Plaintiff in this action, if any, were the result of pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural course of conditions of Plaintiff, or were otherwise due to causes unrelated to Ketek®.

SEVENTH DEFENSE

Plaintiff's claims are preempted by federal or state law, and any regulations or rules promulgated thereunder, including but not limited to the Federal Food, Drug & Cosmetic Act (hereinafter, "FDCA"), 21 U.S.C. § 301. *et. seq.*, and the United States Constitution, Article IV, clause 2.

EIGHTH DEFENSE

Plaintiff's claims are barred, in whole or in part, under the applicable state law because Ketek® was subject to and received pre-market approval by the FDCA under 52 Stat. 1040, 21 U.S.C., § 301 *et seq.*

NINTH DEFENSE

The injuries and damages allegedly suffered by Plaintiff in this action, if any, were the result of nature or other intervening, superseding causes other than this Defendant and, therefore, any alleged action or conduct on the part of this Defendant was not the proximate and/or competent producing cause of the alleged injuries.

TENTH DEFENSE

If Ketek® was involved in the injuries and damages allegedly suffered by Plaintiff in this action, which is denied, the use of Ketek® was improper and/or not in accordance with prescribed, correct procedures. Accordingly, Ketek® was unforeseeably

altered, handled, abused, misused and/or applied for purposes other than those which were indicated, intended or foreseen by this Defendant, thereby barring Plaintiff's claims.

ELEVENTH DEFENSE

Plaintiff's claims are barred because Ketek® was designed, tested, manufactured and labeled in accordance with the state-of-the art industry standards existing at the time, and the risks complained of by Plaintiff were not discoverable using prevailing research and scientific techniques under the then-existing state-of-the art and knowledge and were not discoverable using procedures required by federal or state regulatory authorities charged with supervision of Ketek® as of the time the drug was sold.

TWELFTH DEFENSE

Plaintiff's claims are barred because Ketek® was manufactured, labeled, packaged, advertised, promoted and distributed in accordance with all applicable statutes, codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

THIRTEENTH DEFENSE

Plaintiff failed to exercise reasonable care and diligence to mitigate her injuries and/or damages alleged suffered, if any.

FOURTEENTH DEFENSE

Plaintiff's claims based on any alleged duty to warn are barred against this Defendant based on the "learned intermediary" doctrine.

FIFTEENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because Ketek® is not defective or unreasonably dangerous because it is a prescription pharmaceutical bearing adequate warnings, and is subject to the comment "j" exception to strict tort liability as set forth in § 402A of the Restatement (Second) of Torts (1965); or because it is a prescription pharmaceutical that is unavoidably unsafe pursuant to comment "k" of § 402A of the Restatement (Second) of Torts (1965) or because the Defendant manufacturer provided adequate and complete warnings to Plaintiff's prescribing physicians and, therefore, the product was not defective or unreasonably dangerous pursuant to § 6 of the Restatement (Third) of Torts: Product Liability; or because Ketek® "provides net benefits for a class of patients" within the meaning of comment "f" to § 6 of the Restatement (Third) of Torts: Product Liability; or because of the application of § 4 *et seq.*, of the Restatement (Third) of Torts: Product Liability.

SIXTEENTH DEFENSE

Plaintiff's claims are barred because the utility of Ketek® outweighed its risks.

SEVENTEENTH DEFENSE

Plaintiff's claims must be dismissed because Plaintiff would have taken Ketek® even if the product labeling contained the information that Plaintiff contends should have been provided.

EIGHTEENTH DEFENSE

Plaintiff's claims are barred because Plaintiff did not justifiably rely on activities attributed by Plaintiff to this Defendant in the Complaint, and any injuries or damages complained of in the Complaint were not caused by this Defendant's alleged actions.

NINETEENTH DEFENSE

Plaintiff's claims are barred and/or this Court should defer in this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction and exhaustion of remedies, in that FDA has exclusive or primary jurisdiction over the matters asserted in the Complaint, and is charged under the law with regulating prescription drugs, including Ketek®, and is specifically charged with determining the content of the warnings and labeling for prescription drugs. The granting of the relief prayed for in the Plaintiff's Complaint would impede, impair, frustrate or burden the effectiveness of such federal law and would violate the Supremacy Clause (Art. VI, cl. 2) of the United States Constitution.

TWENTIETH DEFENSE

Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by FDA under the FDCA.

TWENTY-FIRST DEFENSE

The liability of this Defendant, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. This Defendant seek an adjudication of the percentage of fault of the Plaintiff and each and every other person whose fault could have contributed to Plaintiff's alleged injuries and damages, if any.

TWENTY-SECOND DEFENSE

To the extent that application of conflicts of laws rules to the claims asserted in the Complaint yields a legal conclusion that the claims asserted are not governed by the laws relied upon in the Complaint, this Defendant pleads and preserves all defenses which flow from the application of those conflicts rules and which flow from the application of the correct rule of law.

TWENTY-THIRD DEFENSE

Plaintiff's Complaint fails to state a claim against this Defendant upon which relief may be granted and, therefore, must be dismissed.

TWENTY-FOURTH DEFENSE

This Defendant did not breach any duty of care to Plaintiff.

TWENTY-FIFTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because Ketek® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

TWENTY-SIXTH DEFENSE

Plaintiff's claims against this retail seller Defendant are barred by the Illinois Distributor Statute, 735 ILCS 5/2-621.

TWENTY-SEVENTH DEFENSE

Plaintiff's claims against this Defendant are barred as Plaintiff has failed to comply with 735 ILCS 5/2-622 of the Illinois Code of Civil Procedure.

TWENTY-EIGHTH DEFENSE

Plaintiff's claims against this Defendant are barred because the sole proximate cause of any alleged injury to the Plaintiff was something other than the conduct of this Defendant.

TWENTY-NINETH DEFENSE

Persons and/or entities, other than this Defendant, including any Third Party Defendants who will be sued or could have been sued by Plaintiff, are or may be liable to Plaintiff and/or committed certain negligent acts and/or were otherwise at fault, which was the direct and proximate cause of the Plaintiff's alleged injuries and/or damages, including but not limited to death. In the event, and only in the event, that this Defendant is found liable to the Plaintiff, pursuant to 735 ILCS 5/2-1117 of the Illinois Code of Civil Procedure, to the extent that this Defendant's fault is individually less than 25% of the total fault attributable to all persons/entities for the Plaintiff's alleged injuries and/or damages, then this Defendant is only severally liable for the Plaintiff's claimed injuries and/or damages.

THIRTIETH DEFENSE

This Defendant had no duty to warn Plaintiff of any risks associated with her use of the prescription pharmaceutical Ketek®.

JURY DEMAND

Defendant BOND DRUG COMPANY OF ILLINOIS, L.L.C. d/b/a WALGREENS, incorrectly sued as WALGREEN CO. and BOND DRUG COMPANY OF ILLINOIS d/b/a WALGREEN CO., and demands trial by jury of all issues triable by jury.

Respectfully submitted this 11th day of September 2008,

/s/ John A. Childers

John A. Childers

Attorney for defendant, Bond Drug Company of Illinois, LLC, d/b/a Walgreens, incorrectly sued as Walgreen Co. and Bond Drug Company of Illinois d/b/a Walgreen Co.

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CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of September, 2008 I caused to be served true and correct copies of this by causing copies of the same to be served to the following by operation of the CM/ECF System of the U.S. District Court for the Northern District of Illinois:

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/s/ John A. Childers
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